Search results from the "OB Rx" table for query on "019516."

Active Ingredient: MORPHINE SULFATE

Dosage Form; Route: TABLET, EXTENDED RELEASE; ORAL

Proprietary Name: MS CONTIN

Applicant: PURDUE FREDERICK

Strength: 30MG
Application Number: 019516
Product Number: 001

Approval Date: May 29, 1987

Reference Listed Drug

RX/OTC/DISCN:

RX

TE Code:

Patent and Exclusivity Info for this product: View

Active Ingredient: MORPHINE SULFATE

Dosage Form; Route: TABLET, EXTENDED RELEASE; ORAL

Proprietary Name: MS CONTIN

Applicant: PURDUE FREDERICK

Strength: 60MG
Application Number: 019516
Product Number: 002

Approval Date: Apr 8, 1988

Reference Listed Drug

RX/OTC/DISCN:

RX

TE Code:

Patent and Exclusivity Info for this product: View

Active Ingredient: MORPHINE SULFATE

Dosage Form; Route: TABLET, EXTENDED RELEASE; ORAL

Proprietary Name: MS CONTIN

Applicant: PURDUE FREDERICK

Strength: 15MG
Application Number: 019516
Product Number: 003

Approval Date: Sep 12, 1989

Reference Listed Drug
RX/OTC/DISCN:
RX
TE Code:
AB
Patent and Exclusivity Info for this product: View

Active Ingredient: MORPHINE SULFATE

Dosage Form; Route: TABLET, EXTENDED RELEASE; ORAL

Proprietary Name: MS CONTIN

Applicant: PURDUE FREDERICK

Strength: 100MG

Application Number:

019516

Product Number:

004

Approval Date:

Jan 16, 1990

Reference Listed Drug

No

RX/OTC/DISCN:

RX

TE Code:

AB

Patent and Exclusivity Info for this product: View

Active Ingredient:

MORPHINE SULFATE

Dosage Form; Route:

TABLET, EXTENDED RELEASE; ORAL

Proprietary Name:

MS CONTIN

Applicant:

PURDUE FREDERICK

Strength: **Application Number:**

200MG 019516

Product Number:

005

Approval Date:

Nov 8, 1993

Reference Listed Drug

No

RX/OTC/DISCN:

RX

TE Code:

AB

Patent and Exclusivity Info for this product: View

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FDA/Center for Drug Evaluation and Research

Office of Generic Drugs

Division of Labeling and Program Support

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Orange Book Data Updated Through August, 2007

Patent and Generic Drug Product Data Last Updated: September 19, 2007

Search results from the "OB_Rx" table for query on "020553."

Active Ingredient:

OXYCODONE HYDROCHLORIDE

Dosage Form; Route:

TABLET, EXTENDED RELEASE; ORAL

Proprietary Name:

OXYCONTIN

Applicant:

PURDUE PHARMA LP

Strength:

10MG 020553

Application Number: Product Number:

001

Approval Date:

Dec 12, 1995

Reference Listed Drug

No RX

RX/OTC/DISCN:

TE Code:

AB

Patent and Exclusivity Info for this product: View

Active Ingredient:

OXYCODONE HYDROCHLORIDE

Dosage Form; Route:

TABLET, EXTENDED RELEASE; ORAL

Proprietary Name:

OXYCONTIN

Applicant:

PURDUE PHARMA LP

Strength:

20MG

Application Number:

020553 002

Product Number: Approval Date:

Dec 12, 1995

Reference Listed Drug

No

RX/OTC/DISCN:

RX

TE Code:

AB

Patent and Exclusivity Info for this product: View

Active Ingredient:

OXYCODONE HYDROCHLORIDE

Dosage Form; Route:

TABLET, EXTENDED RELEASE; ORAL

Proprietary Name:

OXYCONTIN

Applicant:

PURDUE PHARMA LP

Strength:

40MG

Application Number:

020553

Product Number:

003

Approval Date:

Dec 12, 1995

Reference Listed Drug

Yes RX

RX/OTC/DISCN:

TE Code:

AB

Patent and Exclusivity Info for this product: View

Active Ingredient:

OXYCODONE HYDROCHLORIDE

Dosage Form; Route:

TABLET, EXTENDED RELEASE; ORAL

Proprietary Name:

OXYCONTIN

Applicant:

PURDUE PHARMA LP

Strength:

80MG

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Application Number:

020553

Product Number:

004

Approval Date:

Jan 6, 1997

Reference Listed Drug

No

RX/OTC/DISCN:

RX

TE Code:

AB

Patent and Exclusivity Info for this product: View

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Patent and Exclusivity Search Results from query on Appl No 020553 Product 001 in the OB_Rx list.

Patent Data

Appl	Prod	Patent	Patent	Drug Substance	-	
No	No	No	Expiration	Claim	Claim	Code
020553	001	4861598	AUG 29,2006			
020553	001	4970075	AUG 29,2006			
020553	001	5266331	OCT 26,2007		Υ	
020553	001	5508042	APR 16,2013			<u>U-443</u>
020553	001	5549912	OCT 26,2007		Y	
020553	001	5656295	OCT 26,2007			<u>U-443</u>

Exclusivity Data

There is no unexpired exclusivity for this product.

Additional information:

- 1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
- 2. Patents submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor and are detailed in the above table.
- 3. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply
- 4. *PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with *PED as was done prior to August 18, 2003. Patents with *PED added after August 18, 2003 will not contain any information relative to the patent itself other than the *PED extension. Information related specifically to the patent will be conveyed on the original patent only.
- 5. U.S. Patent Nos. RE 36481 and RE 36520 were relisted for Zocor (NDA 19-766) pursuant to the decision and related order in Ranbaxy Labs. v.Leavitt, No. 05-1838 (D.D.C. April 30, 2006). The '481 and '520 patents remained listed in Approved Drug Products with Therapeutic Equivalence Evaluations until any applicable periods of exclusivity pursuant to section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act were triggered and run. For additional information on this matter, please refer to Docket Nos. 2005P-0008 and 2005P-0046. Patents were subsequently delisted in the December 2006 Orange Book update as the exclusivity periods have triggered and run to expiration.

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